

U.S. Patent Application Serial No. 10/776,409
Filed: February 10, 2004
AMENDMENT AND RESPONSE TO FIRST OFFICE ACTION
Page 10 of 19

REMARKS

The claims of the present application are directed to systems and devices for stabilization of an implant in bone tissue of a human or an animal. Prior to this Response, Claims 1-51 were pending. In this Response, Applicant cancels Claims 15-23 and 42-51 as non-elected and withdrawn from consideration. Applicant also cancels Claim 29, amends Claims 1, 3, 7-12, 14, 24-27, 30-35 and 38-39, and adds new Claims 52-63. Claims 1-14, 24-28, 30-41 and 52-63 will be pending upon entry of the amendments.

Support for the Amendments to the Specification

Applicant amends the specification to correct an unintentional typographical error. Support for the amendment is found in the U.S. Provisional Patent Application No. 60/446,210 filed February 10, 2003, of which the present application claims the benefit of priority, and which is incorporated in the specification of the present application in its entirety. Accordingly, the amendments to the specification do not introduce any new matter.

Support for the Amendments to the Claims and the New Claims

Support for the claim amendments and the new claims is found throughout the application, as filed. For example, currently amended Claim 1 is supported in the specification on p. 20, lines 19-20, and p. 21, line 28. Currently amended Claims 3, 26 and 35 are supported in the specification, for example, on p. 17, line 24. Currently amended Claim 7 is supported in the specification, for example, on p. 20, lines 19-24. Currently amended Claim 8 is supported in the specification, for example, on p. 20, lines 2-5. Currently amended Claim 10 is supported in the specification, for example, on p. 21, lines 10-17. Currently amended Claim 24 is supported in the specification, for example, on p. 23, lines 13-17, p. 24, lines 16-21, p. 25, lines 20-24, and p. 26, line 8. Currently amended Claim 24 is supported in the specification, for example, on p. 23, lines 13-17, p. 24, lines 16-21, p. 25, line 1, and p. 26, line 8. Currently amended Claim 38 is supported in the specification, for example, on p. 6, line 8, claim 23, line 13-17. New Claim 53 is based on Claim 30, as filed, and further supported, for example, in the specification on p. 25, line 15. New Claim 54 is supported, for example, in the specification on p. 25, lines 5-17. New

U.S. Patent Application Serial No. 10/776,409
Filed: February 10, 2004
AMENDMENT AND RESPONSE TO FIRST OFFICE ACTION
Page 11 of 19

Claims 55 and 56 are supported, for example, in the specification on p. 25, lines 20-22. New Claims 57 and 58 are supported, for example, in the specification on p. 25, line 23. New Claims 59-61 are supported, for example, in the specification on p. 22, line 9, through p. 23, line 3. New Claim 62 is based on Claim 24 as currently amended. New Claim 63 is based on Claims 1 and 7, as currently amended. Additionally, the claims have been amended for clarity and to correct informalities. Accordingly, the claim amendments and the new claims do not introduce any new matter.

Election/Restriction

The Office Action acknowledges Applicant's invention without traverse of Claims 1-14 and 24-41. The Office Action withdraws Claims 15-23 and 42-51 from further consideration as drawn to a non-elected invention. *See* Office Action, page 2. In this Response, Applicant cancels Claims 15-23 and 42-51 as non-elected and without prejudice.

Claim Rejections under 35 U.S.C. §101

The Office Action rejects Claims 1-14 and 24-41 under 35 U.S.C. §101. The Office Action asserts that the claims are drawn to non-statutory subject matter. Applicant respectfully traverses the rejection. Applicant cancels Claim 29, rendering its rejection moot. Applicant asserts that Claims 1-14, 24-28 and 30-41 are directed to statutory subject matter in the class "machine" provided under 35 U.S.C. §101, and the rejection should be withdrawn for at least this reason.

The Office Action asserts on page 2 that Claims 1-14 and 24-41 "include a human within their scope and are non-statutory" because Claim 1 recites "wherein the resorbable device is inserted into a cavity between the implant and the bone tissue of the human or the animal," and because Claims 24 and 33 recite "wherein the at least one resorbable component is at least partially inserted into the bone tissue." Applicant disagrees.

U.S. Patent Application Serial No. 10/776,409
Filed: February 10, 2004
AMENDMENT AND RESPONSE TO FIRST OFFICE ACTION
Page 12 of 19

35 U.S.C. §101 provides:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Applicant respectfully asserts that Claims 1-14, 24-28 and 30-41 are directed to subject matter in the statutory class "machine" provided under 35 U.S.C. §101. Claim 1 and its dependent claims are directed to a system for stabilization of an implant in bone tissue of a human or an animal comprising a resorbable device. The system and its components recited in Claim 1 are in the statutory class "machine" provided under 35 U.S.C. §101. Claim 24 and its dependent claims are directed to a hybrid resorbable device for stabilization of a prosthetic implant in bone tissue of a human or an animal. The device recited in Claim 24 is in the statutory class "machine" provided under 35 U.S.C. §101. Claim 33 and its dependent claims are directed to a prosthetic implant system comprising a prosthetic implant and a hybrid resorbable device for stabilization of the prosthetic implant in bone tissue. The system and the components recited in Claim 33 are in the statutory class "machine" provide under 35 U.S.C. §101.

The Office Action asserts that the claims include within their scope a human, a non-patentable subject matter under 35 U.S.C. §101. Applicant disagrees. The claims recite bone tissue in order to define the configuration of the claimed system or device, and not as a component of the claimed system or device. Specifically, the language "wherein the resorbable device is of a shape suitable for insertion into a cavity formed between the prosthetic implant and the bone tissue of the human or the animal" is recited in currently amended Claim 1 in order to define the relative configuration of the statutory components, "prosthetic implant" and "resorbable device." The language "wherein the at least one resorbable component is adapted to be at least partially inserted into the bone tissue" and "wherein the at least one resorbable component is configured to be at least partially inserted into the bone tissue," recited in currently amended Claims 24 and 33, respectively, in order to define the configuration of the statutory component of the resorbable component relative to the bone. Also, to clarify the claim, Applicant amends Claim 24 to recite "at least one resorbable component adapted to be at least

U.S. Patent Application Serial No. 10/776,409
Filed: February 10, 2004
AMENDMENT AND RESPONSE TO FIRST OFFICE ACTION
Page 13 of 19

partially inserted into the bone tissue.” “Bone tissue: recited in the claims is not a component of the claimed systems and devices.

Applicant does not claim “bone tissue” as an embodiment of his invention and does not attempt to exclude others from the use of bone tissue. Accordingly, Applicant respectfully asserts that allowing Claims 1-14, 24-28 and 30-41 to issue would not violate the principles of 35 U.S.C. §101. While Congress meant 35 U.S.C. §101 to exclude non-statutory items from even temporary monopolization by patent, the claims should be allowed to issue when they do not prohibit all uses of the non-statutory items. *In re Bernhart and Fetter* 163 U.S.P.Q. 611, 616 (1969). Here, allowing Claims 1-14, 24-28 and 30-41 would not exclude others from using bone tissue.

In view of the foregoing, Applicant requests withdrawal of the rejection of Claims 1-14 and 24-41 under 35 U.S.C. §101.

Claim Rejections under 35 U.S.C. §102(b)

The Office Action rejects Claims 1-10 and 24-41 under 35 U.S.C. §102(b) in light of U.S. Patent No. 5,571,193 to Kampner (“*Kampner*”). Applicant cancels Claim 29, rendering its rejection moot. Anticipation requires the cited reference to teach each and every element of the claim. See MPEP 2131.01. *Kampner* does not teach at least the following elements recited in Claims 1-10, 24-28 and 30-41, or any other pending claims. With regard to Claim 1 and its dependent claims, *Kampner* does not teach a resorbable device of a shape suitable for insertion into a cavity formed between an implant and bone tissue after installation of the implant. With regard to Claims 24 and 33 and their respective dependent claims, *Kampner* does not teach a hybrid resorbable device for stabilization of a prosthetic implant in bone tissue, comprising at least one resorbable component adapted to be at least partially inserted into the bone tissue and at least one non-resorbable component adapted to cover the at least one resorbable component upon at least partial insertion of the at least one resorbable component into the bone tissue. At least in view of the foregoing, *Kampner* fails to anticipate pending claims.

U.S. Patent Application Serial No. 10/776,409
Filed: February 10, 2004
AMENDMENT AND RESPONSE TO FIRST OFFICE ACTION
Page 14 of 19

Kampner discloses two types of resorbable devices in relation to prosthetic hip joints. One type of a resorbable device disclosed in *Kampner* is a resorbable sleeve surrounding of a non-resorbable core, together forming a "composite anchor" or stem of a prosthetic implant. See, for example, *Kampner*, column 3, lines 20-60, Figures 1-6 (see, in particular, items 4, 6 and 8 in Figure 1, items 38, 44 and 46 in Figures 2 and 3, items 74, 76, 78, 92, 94 and 96 in Figure 4) and corresponding description in columns 5 through 10. Another type of device as disclosed in *Kampner* is resorbable screws. See *Kampner*, column 6, lines 59-60 through column 7, line 4, item 20 in Figure 1, and item 54 in Figures 2 and 3. For easy reference, a copy of Figure 1 of *Kampner* is provided.

The composite anchor in *Kampner* is designed to be put together and assembled with the other components of the implant prior to installation of the implant. Upon assembly, the composite anchor of the implant is press-fitted into the intramedullary canal. See, for example, *Kampner*, column 5, lines 51-64, column 7, lines 23-33, and column 8, lines 49-67. In other words, *Kampner* teaches that the resorbable component of the anchor (sleeve) is selected and assembled with the non-resorbable component of the anchor (core), and the anchor is then assembled with the other components of the prosthetic implant prior to insertion of the implant into intramedullary cavity. In fact, it would be impossible to insert the resorbable sleeve as shown in Figures 1-4 in *Kampner* after insertion of the non-resorbable core due to the configuration of the system. In reference to Figure 1 of *Kampner*, please note that either the resorbable sleeve's, item 4, closed bottom end, or the implant's trochanteric body piece, item 2, prevents the possibility of inserting the sleeve after installation of the femoral component of the hip implant, item 1A, into the intramedullary canal of the femur.

Claims 1-14, rejected in the Office Action in view of *Kampner*, are directed to a system for stabilization of an implant in bone tissue of a human or an animal, comprising a prosthetic implant and a resorbable device adapted to be placed between the prosthetic implant and the bone tissue. The systems recited in rejected Claims 1-14 and new Claim 63 comprise resorbable devices that are shaped to be inserted into a cavity between a bone and a prosthetic implant after the implant is installed, in order to provide additional stabilization of the implant with respect to the bone. New Claims 59-61 are directed to embodiments of such systems adapted for

U.S. Patent Application Serial No. 10/776,409

Filed: February 10, 2004

AMENDMENT AND RESPONSE TO FIRST OFFICE ACTION

Page 15 of 19

stabilization of a prosthetic hip. As discussed above, the resorbable sleeves disclosed in *Kampner* cannot be inserted after installation of the implant and cannot be used for additional stabilization after the installation of the implant, should such a need arise. According to *Kampner*, its resorbable sleeves are specifically adapted for temporary distal immobilization in proximally fixed implants. See, for example, *Kampner*, column 7, lines 39-59.

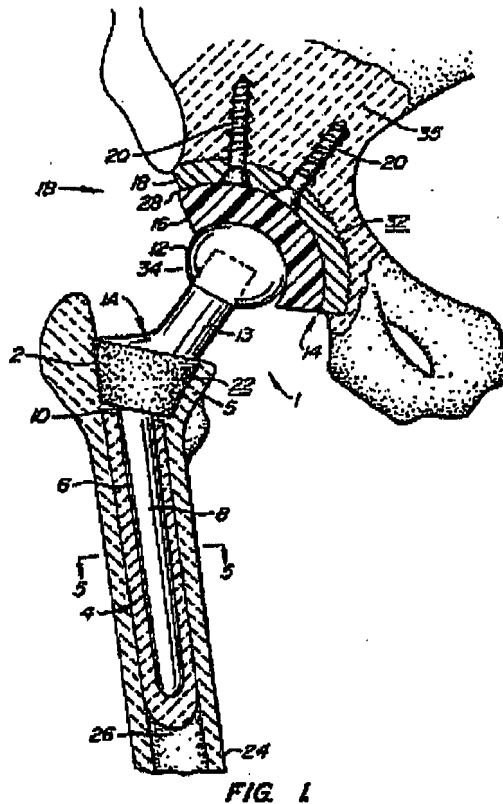


FIG. 1

Figure 1, *Kampner*

Unlike the resorbable sleeves in *Kampner*, Applicant's resorbable devices, as recited in Claims 1-14, 59-61 and 63 allow for additional stabilization of a conventional implant after its installation, including proximal stabilization of a distally fixed implant, as recited in Claims 14 and 61, if such a need arises. *Kampner* fails to teach systems comprising resorbable devices suitable for insertion into a cavity between a bone and a prosthetic implant after installation of the prosthetic implant, and fails to anticipate Claims 1-14, 59-61 and 63 for at least this reason.

U.S. Patent Application Serial No. 10/776,409

Filed: February 10, 2004

AMENDMENT AND RESPONSE TO FIRST OFFICE ACTION

Page 16 of 19

Claims 24-28 and 30-41, rejected in the Office Action in view of *Kampner*, are directed to hybrid resorbable devices or systems comprising such devices, the devices comprising at least one resorbable component adapted to be at least partially inserted into the bone tissue and the at least one non-resorbable component adapted to cover the at least one resorbable component upon at least partial insertion of the at least one resorbable component into the bone tissue. The resorbable sleeve disclosed in *Kampner* is not adapted for at least partial insertion into the bone tissue, unlike the resorbable component of the hybrid devices recited in Claims 24-28 and 30-41, and also in the new Claims 53-58. The resorbable sleeve disclosed in *Kampner* is also not a resorbable screw, peg, pin, spike, needle or pin, all recited as variants of at least one resorbable component of a hybrid resorbable device in Claim 62. Accordingly, the implant comprising a resorbable sleeve as disclosed in *Kampner* fails to anticipate Claims 24-28, 30-41, 53-58 and 62 for at least the above reasons.

Another type of a resorbable device disclosed in *Kampner* is resorbable screws. See *Kampner*, column 6, lines 59-60 through column 7, line 4. The resorbable screws in *Kampner* appear to be conventional resorbable screws as discussed in the present application on page 10, lines 8-27. With regard to Claims 1-14, 59-61 and 63 the resorbable screws in *Kampner* are clearly different from the resorbable devices recited in these claims as the resorbable screws are not of a shape suitable for insertion into a cavity formed between the prosthetic implant and the bone tissue of the human or the animal after installation of the implant in order to immobilize the implant. Accordingly, the disclosure regarding the resorbable screws in *Kampner* fails to anticipate Claims 1-14, 59-61 and 63 for at least this reason.

With regard to Claims 24-28, 30-41, 53-58 and 62, the resorbable screws in *Kampner* are not hybrid resorbable devices and they do not comprise at least one resorbable component adapted to be at least partially inserted into the bone tissue and the at least one non-resorbable component adapted to cover the at least one resorbable component upon at least partial insertion of the at least one resorbable component into the bone tissue, as recited in the rejected claims and also new Claims 53-58. New Claim 62, which is also directed to a hybrid resorbable device, is not anticipated by *Kampner* at least because it recites at least one non-resorbable component of a hybrid resorbable device, adapted to cover the at least one resorbable component upon at least

U.S. Patent Application Serial No. 10/776,409
Filed: February 10, 2004
AMENDMENT AND RESPONSE TO FIRST OFFICE ACTION
Page 17 of 19

partial insertion of the at least one resorbable component into the bone tissue. Accordingly, the disclosure of the resorbable screws in *Kampner* fails to anticipate pending claims for at least the above reasons.

In view of the foregoing, Applicant requests withdrawal of the rejection of Claims 1-10 and 24-41 under 35 U.S.C. §102(b) in light of *Kampner*.

Claim Rejections under 35 U.S.C. §103(a)

The Office Action rejects Claims 11-14 under 35 U.S.C. §103(a) in light of U.S. Patent No. 5,571,193 to *Kampner* ("*Kampner*") in view of U.S. Patent No. 6,827,743 to *Eisermann et al.* ("*Eisermann*"). A *prima facie* case of obviousness based on a reference or references must meet three basic criteria: (1) suggestion or motivation to modify the reference or to combine the references' teachings; (2) a reasonable expectation of success from such a combination or modification; and, (3) the reference or references must teach or suggest all the claim limitations. See MPEP 2141.01(a) and 2142. The rejection based on a combination of *Kampner* and *Eisermann* does not meet at least two of the three required *prima facie* obviousness criteria, showing of the teaching or suggestion in the references of all the claim limitations, and showing of the motivation to combine the cited references. Thus, *Kampner* or *Eisermann*, separately or in combination, fail to render the claims obvious for at least the above reasons.

The Office Action states that "*Kampner* discloses the claimed invention except an orthopedic cable," and *Eisermann* discloses an orthopedic cable recited in the rejected claims. Applicant explains in the previous section why *Kampner* fails to disclose the systems and devices recited in the pending claims. *Kampner* also fails to suggest or provide motivation to derive the systems and devices recited in the pending claims. *Eisermann* relates to orthopedic implants made from mesh materials and fails to teach or suggest any resorbable components of orthopedic implants. In fact, *Eisermann* specifically contemplates non-resorbable materials for the mesh implants. See, for example, *Eisermann*, column 2, lines 18-33. Accordingly, *Kampner* or *Eisermann*, separately or in combination, fail to teach or suggest all elements of the pending claims. The Office Action therefore fails to establish a *prima facie* case of obviousness for at least this reason and the rejection should be withdrawn.

U.S. Patent Application Serial No. 10/776,409
Filed: February 10, 2004
AMENDMENT AND RESPONSE TO FIRST OFFICE ACTION
Page 18 of 19

The Office Action also fails to show any suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings, and fails to show there would be a reasonable expectation of success when the references are combined. *See KSR Intern. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (U.S. 2007) and *Leapfrog Enters., Inc., v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007). The Office Action merely states that “[i]t would have been obvious to one skilled in the art at the time the invention was made to construct the device of Kampner with an orthopedic cable, in view of Eisermann et al., to secure the implant to the bone.” The Office Action offers nothing further as a factual or legal basis for such a combination. To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention, or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. *See* MPEP § 706.02(j). The Office Action does not satisfy this requirement. A *prima facie* case of obviousness is not sufficiently established by stating that the claimed invention would have been within the knowledge of one of ordinary skill in the art. *In re Kozab*, 217 F.3d 1365, 1271, 55 USPQ 2d 1313, 1318 (Fed. Cir. 2000); *see also* MPEP § 2143.01. The Office Action fails to show suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings, as required for a showing of *prima facie* obviousness. The rejection should therefore be withdrawn for at least this reason.

Based on the foregoing, Applicant requests withdrawal of the rejection of Claims 11-14 under 35 U.S.C. §103(a) in light of *Kampner* in view of *Eisermann*.

U.S. Patent Application Serial No. 10/776,409
Filed: February 10, 2004
AMENDMENT AND RESPONSE TO FIRST OFFICE ACTION
Page 19 of 19

CONCLUSION

In light of the amendments and the above remarks, Applicant is of the opinion that the Office Action has been completely responded to and that the application is now in condition for allowance. Such action is respectfully requested.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned agent at (404) 815-6102 is respectfully requested.

Respectfully submitted,



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